REMARKS

Interviews

Applicant would like to thank Examiner's Huynh and Chan for granting a telephone interview on August 8, 2006 and a follow-up interview with Examiner Huynh on September 11, 2006. The incorporation by reference of the teachings of U.S. Serial No. 09/141, 220 was discussed as were the prior art rejections. This response incorporates the arguments that were presented and the conclusions that were reached in those interviews (discussed in more detail below). Examiner Huynh indicated that she would review the rejections of the final office action in light of these arguments and conclusions.

Amendments to the claims

Claim 34 has been amended to specify that the modified peanut allergen is encapsulated inside the dead *E. coli*. As discussed during the interview that was held on September 11, 2006, this amendment is supported by description that can be found in the original specification on page 12, lines 7-16 (which highlights the advantages of delivering allergens that are encapsulated inside microorganisms) and page 16, line 22 to page 17, line 3 (which describes *inter alia* the secretion of allergens into the periplasm).

Claim 45 has been amended to recite the killing of *E. coli* with "alcohol" instead of "alcohols". In a final office action for related application U.S. Serial No. 10/728,323, the Examiner noted that such an amendment would be appropriate since the claim refers to singular chemical treatment. It is to be understood that as amended, the term "alcohol" in claim 47 encompasses both a single alcohol and a mixture of alcohols.

No new matter is being added.

Rejection under 35 U.S.C. § 112, first paragraph for lack of enablement

The Examiner has maintained the rejection of claims 34-42 for lack of enablement and added new claims 43-45 to the rejection. This rejection is respectfully traversed; reconsideration and withdrawal is requested.

The rejected claims relate to pharmaceutical compositions that include a pharmaceutically acceptable carrier and a modified peanut allergen Ara h 1, 2 or 3 that is encapsulated inside dead *E. coli* cells. The amino acid sequence of the modified peanut allergen differs from that of the wild-type peanut allergen and as a consequence it has a reduced ability to bind to or cross-link IgE antibodies. As described in the application, these compositions are useful for treating allergy. The Examiner argues that, despite the extensive teachings in the present application, this invention was so unpredictable at the time of filing that a skilled person could not have made and used the claimed invention without an undue amount of experimentation.

In the previous office action, the Examiner had raised two alleged sources of unpredictability, namely: (1) the immunological properties of the claimed compositions and (2) the modification of peanut allergens to reduce IgE binding. In response, Applicant provided detailed arguments that addressed each of these three alleged sources of unpredictability (see response filed November 4, 2005).

In the most recent and final office action the Examiner began by repeating the earlier rejection (see pages 2-5). The Examiner then turned to Applicant's response but only discussed arguments that were presented for the second of these alleged sources, namely the modification of allergens to reduce IgE binding (see pages 6-9). Even then, the Examiner never *addressed* Applicant's arguments on this issue. Instead, the majority of the Examiner's discussion consisted of repeating (yet again) the earlier rejection, specifically by referring to alleged "failures" in Applicant's own peptide mutational studies with peanut allergens Ara h 1 (Burks et al.) and Ara h 2 (Stanley et al.). As discussed in the response that was filed November 4, 2005, these references do not demonstrate that making modified peanut allergens with reduced IgE binding is so unpredictable that undue experimentation would be required. Specifically, Applicant previously noted that the Examiner was wrong to focus on the supposed "failures" while disregarding the vast number of "successes" that are described in those references. In addition, Applicant noted that the Examiner's argument did not take into account the nature and amount of experimentation that would actually be required to identify suitable modifications that

are not explicitly described in the application or in the prior art. Specifically, Applicant cited *Wands*, in which the Federal Circuit held that when the starting materials are readily available and the experimentation is of a *routine* nature then the level of experimentation is not undue. *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988). Applicant then highlighted the parallels that exist between the routine experimentation in *Wands* and the routine experimentation that would be required in this case. The Examiner has not yet addressed any of these points. Repeating earlier arguments is insufficient. As noted, under MPEP 707.07(f), "[w]here the applicant traverses any rejection, the Examiner should, if he or she repeats the rejection, take note of the applicant's argument and *answer the substance of it*" (*emphasis* added). The Examiner has failed to meet this burden.

The one argument that the Examiner did address relates to the incorporation by reference of U.S. Serial No. 09/141,220 (the '220 application). This application was filed by Applicant in 1998 and describes the modification of the peanut allergens Ara h 1, 2 and 3. It was incorporated by reference on page 20, line 29 to page 21, line 1 of the present application to provide explicit description of modified peanut allergens with reduced IgE binding. In the response that was filed on November 4, 2005, Applicant referred to this incorporation by reference as additional support for the enablement argument. In response, the Examiner stated that the incorporation by reference was improper because it was to a pending application that "may or may not be issued as a patent" (see page 9 of final office action).

During the interview that was held on August 8, 2006, Applicant's representatives explained to the Examiner that at the time the present application was filed (i.e., December 4, 2003) one could incorporate any material by reference to a pending U.S. application. In support of this, Applicant faxed a copy of § 608.01(p) from the 2001 version of the MPEP (copy attached as **Exhibit A**). In the facsimile, Applicant noted that an application could "incorporate 'essential material' by reference to [...] a pending U.S. application" (referring to on page 600-79). Applicant also faxed a copy of § 608.01(p) from the most current version of the MPEP (copy attached as **Exhibit B**). This version mentions that "prior to October 21, 2004, Office policy also permitted incorporation by reference to a pending U.S. application."

Applicant also noted in the facsimile that if the referenced application has not been published or issued as a patent at the time of allowance then "applicant will be required to amend

the disclosure of the referencing application to include the material incorporated by reference" (referring to page 600-80). In this case, the incorporated '220 application has been abandoned and, as discussed during the interview, Applicant would be willing to amend the specification of this application to include the material incorporated by reference. Finally, Applicant noted that even under the current version of the MPEP, incorporation by reference of an unpublished patent application can be corrected under 37 CFR § 1.57(g):

> An incorporation by reference of essential material to an *unpublished U.S. patent application*, a foreign application or patent, or to a publication is improper under 37 C.F.R. 1.57(c). The improper incorporation by reference is not effective to incorporate the material *unless corrected by the applicant* (37 C.F.R. 1.57(g)). Any underlying objection or rejection (e.g., under 35 U.S.C. 112) should be made by the Examiner until *applicant corrects the improper incorporation by reference by submitting an amendment to amend the specification or drawings to include the material incorporated by reference.* A statement that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter is also required. 37 C.F.R. 1.57(f).

During a follow-up interview that was held on September 11, 2006, the Examiner indicated that the incorporation by reference was indeed proper and that she would reconsider Applicant's arguments in light of this. For all of these reasons, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of claims 34-45 for lack of enablement.

Rejection under 35 U.S.C. § 112, first paragraph for lack of written description

The Examiner has maintained the rejection of claims 34-42 for lack of written description and added new claims 43-45 to the rejection. This rejection is also respectfully traversed; reconsideration and withdrawal is requested.

In responding to Applicant's arguments, the Examiner argues that Applicant was not in possession of the claimed invention at the time of filing because: "[u]ntil the structure of the modified peanut allergens with reduced IgE binding present in *E. coli* has been described, the specification as filed merely ask [sic] one of skilled [sic] in the art to come up with the structure of the modified peanut allergen for the claimed composition" (see page 12 of final office action). Notably, on page 12, the Examiner also states that:

> "The specification does not describe any modified Ara h1, Ara h2 and/or Ara h3 contained in *E. coli* as a pharmaceutical composition. As stated earlier, USSN

09/141,220 has not been issued as a patent and therefore information containing [sic] therein incorporated by reference is not available to the public."

As discussed during the interviews, this last statement is incorrect – the incorporation by reference of U.S. Serial No. 09/141,220 was proper and the specification does therefore include explicit and extensive description of representative modified Ara h 1, 2 and 3 peanut allergens. Applicant respectfully requests that the Examiner reconsider this rejection in light of these teachings.

In this context, the Examiner is reminded that a claim limited to modified peanut allergens with the particular substitutions that the inventors happened to have made prior to filing their patent application is virtually useless. Anybody of ordinary skill in the art could prepare a modified peanut allergen that falls outside the scope of such a claim but still embodies the spirit, scope, and teachings of applicant's *contribution.* If the legal standard of written description in fact required verbatim recitation of every possible useful sequence, as asserted by the Examiner, patent applicants would be forced to perform useless and wasteful experiments (potentially endlessly) merely to ensure that they could protect their contributions. Such a standard would eviscerate the patent system. The Examiner's rejection of claims 34-45 for lack of written description should be removed.

Rejections of claims 34-43 under 35 U.S.C. § 103 for obviousness

The Examiner has rejected claims 34-43 under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 5,888,799 ("the '799 patent") in view of WO 99/38978 ("the '978 publication") and Yeung et al. ("Yeung"). This rejection is respectfully traversed; reconsideration and withdrawal is requested.

The Examiner begins by citing the '799 patent as a primary reference that teaches a composition comprising live bacteria such as *E. coli* that contain any allergen and a pharmaceutically acceptable carrier (see page 13 of office action). The Examiner then cites the '978 publication for teaching live *E. coli* that contain a modified peanut allergen Ara h 1, 2 or 3 (see page 14 of office action). Finally, the Examiner cites Yeung for teaching that heat-killed *Listeria monocytogenes* acts as an adjuvant that can bias an allergic reaction towards a Th1-type

response (see pages 14-15 of office action).

The Examiner then argues that it would have been obvious to produce the claimed invention by (a) substituting the live *E. coli* of the '799 patent with the live *E. coli* of the '978 publication and then (b) heat-killing the *E. coli* as taught by Yeung (see page 15 of office action). This rejection is respectfully traversed; reconsideration and withdrawal is requested.

The identical rejection was originally made by the Examiner in an office action that was mailed on September 14, 2005 for related case U.S. Serial No. 10/728,323. The rejection was addressed by Applicant in a response that was filed in that case on March 14, 2006 and the Examiner maintained the rejection in a final office action that was mailed on June 2, 2006. In order to expedite prosecution of this particular case, Applicant hereby incorporates by reference the arguments that were made in the response that was filed on March 14, 2006 in related case U.S. Serial No. 10/728,323. Here, Applicant will address the counterarguments that have already been made in that case by the Examiner in the final office action mailed June 2, 2006.

The response that was filed by Applicant on March 14, 2006 in related case U.S. Serial No. 10/728,323 discussed the deficiencies of substitution step (a). In particular, Applicant noted that the potent immunological nature of the anaphylactic peanut allergens of the '978 publication would have discouraged one of ordinary skill in the art from attempting to substitute them into the methods of the '799 patent that have only been described for tamer antigens such as isolated microbial antigens and non-anaphylactic allergens (e.g., from animal danders and pollens, see column 9, line 59 to column 10, line 6 of the '799 patent). In the final office action that followed that response, the Examiner simply noted that while the '799 patent does not teach expressing anaphylactic allergens, the '978 publication "teaches expressing anaphylactic modified allergens such as Ara h 1, Ara h 2 and Ara h 3 in live *E. coli*". Applicant does not understand the Examiner's point. Is the Examiner implying that the teachings of the '799 patent are no longer required, i.e., that the combined teachings of the '978 publication and Yeung are sufficient to yield the claimed invention? If so, then why does the rejection refer to the '799 patent? The '978 publication does indeed teach the expression of modified Ara h 2 in *E. coli* but the '978 publication uses *E. coli* as a recombinant production system that is lyzed and discarded once the modified Ara h 2 has been produced (see page 16, line 22 to page 17, line 9). The '978 publication therefore cannot teach or suggest the presently claimed composition wherein a

modified peanut allergen is *encapsulated* inside *dead E. coli*. Indeed, the '978 publication teaches away from such a composition. Applicant therefore submits that, at a minimum, clarification of the Examiner's proposed substitution step (a) is required. If indeed the Examiner is relying on the '978 publication to teach peanut allergens in *E. coli*, then such teachings are wholly insufficient to teach or suggest the claimed compositions in which modified peanut allergens are *encapsulated* inside *dead E. coli.* and the rejection should be removed.

Heat-killing step (b) of the Examiner's *prima facie* case of obviousness is also deficient. Yeung teaches that when heat-killed *Listeria monocytogenes* (HKL) is mixed with the keyhole limpet hemocyanin antigen (KLH) it acts as an adjuvant that can bias an allergic reaction towards a Th1-type response (e.g., see abstract). There is some discussion of *mixing* HKL with other antigens including allergens in Yeung; however, there is no teaching or suggestion of incorporating KLH or other antigens *inside* heat-killed *Listeria monocytogenes* or any other heat-killed microorganism. Applicant does not see how these teachings would motivate the skilled person to prepare dead *E. coli* that include *encapsulated* allergens (let alone modified peanut allergens). The only logical modification of the teachings of the '799 patent based on the teachings of Yeung would be to administer a *mixture* of HKL with the live *E. coli* cells of the '799 patent. Similarly, the only logical modification of the teachings of the '978 publication by combination with Yeung would be to administer a *mixture* of HKL with the naked modified peanut allergens of the '978 publication. Neither one of these combinations produces the claimed invention. Crucially, these combinations would be motivated by the explicit teachings of Yeung, namely on page 4151 where they state:

> Since disease improvement with allergen immunotherapy is associated with the reduction of allergen-specific IL-4 synthesis [...], and since HKL is potent in reducing Ag-specific Th2-dominated immune responses and Ag-specific IgE synthesis, *modification of conventional allergen immunotherapy to include adjuvants such as HKL* may render allergen immunotherapy more efficacious (emphasis added).

During the interview, Applicant's representatives also emphasized that the "containing therein" language in the then pending claims was intended to cover compositions in which the modified peanut allergen is *encapsulated inside* the dead *E. coli* (i.e., within the cytoplasm or periplasm). As discussed in the application (e.g., see page 12, lines 7-16), this encapsulation has the advantage of protecting the modified peanut allergen from unwanted interactions until the *E.*

coli cells have been digested, thereby reducing the likelihood of an adverse reaction. The Examiner argued that the claim language was ambiguous on this point and suggested that Applicant amend the claims to expressly refer to this encapsulation. As noted above, the claims have been amended accordingly.

Based on the foregoing it is apparent that the combination of the '799 patent, the '978 publication and Yeung fails to establish a *prima facie* case of obviousness. The Examiner's rejection of claims 34-43 under 35 U.S.C. § 103(a) in light of these references should therefore be removed.

Rejection of claims 44-45 under 35 U.S.C. § 103 for obviousness

Claims 44-45 were rejected under 35 U.S.C. § 103 as being unpatentable over the '799 patent in view of the '978 publication and Yeung and further in view of U.S. Patent 6,270,723 ("the '723 patent") or Evans et al. ("Evans"). This rejection is respectfully traversed; reconsideration and withdrawal is requested. The combination of the '799 patent, the '978 publication and Yeung with the '723 patent and Evans are discussed in turn.

'723 patent

The '723 patent is a secondary reference that was cited solely as teaching elements or limitations that are present in dependent claims 44-45 (namely that the dead *E. coli* was killed with a chemical such as alcohol). Specifically, the '723 patent was cited as teaching methods of killing *E. coli* with chemicals including alcohol. The Examiner states that these methods are taught by '723 patent in the context of improving the safety of vaccines (see page 16 of final office action). These statements are misleading. The '723 patent teaches methods for sterilizing, decontaminating, or disinfecting materials (i.e., improving their safety) and methods for preparing vaccines that are more immunogenic than by prior art methods (e.g., see abstract). It does refer to prior art methods which involve heat and chemicals (e.g., see column 1, lines 24-23). However, the '723 patent itself teaches a new "cryobaric" method which involves repeatedly cycling between relatively high and low pressures at low temperatures (e.g., see abstract). One of the advantages of this pressure based method is that it avoids denaturing proteins as compared to heat or chemical treatment and thereby enhances the immunogenicity of

the resulting vaccine (e.g., see column 5, lines 30-36). If anything, the '723 patent therefore teaches away from the prior art uses of chemicals and heat. For example, in column 9, lines 1-15 it teaches:

> A successful vaccine preparation method should ideally result in a high degree of pathogen inactivation, but should allow the solution of pathogen to retain its ability to stimulate a protective immune response in the patient. Cryobaric procedures are well suited to meet the criteria needed for successful vaccine production: *since cold, pressure-denatured proteins retain a more native-like structure than do heated or chemically-denatured proteins, pressure inactivated pathogens can thus be more immunogenic.* Pressure-denatured proteins are also less likely to aggregate, thereby providing higher yields of vaccine. The pressure-inactivation methods described herein can be economical on a large scale since there are generally *no chemicals* to add or remove and, *unlike heat,* pressure can be transmitted rapidly through a large sample.

On page 16 of the office action, the Examiner cites to this very passage and implies that the touted benefits can be obtained through *chemical* treatment. As can be seen from the section itself, the '723 patent teaches quite the opposite. If anything, one could argue that the teachings of the '723 patent might motivate the skilled person to kill the *Listeria* of Yeung with this cryobaric method instead of heat. However, even if this motivation did exist, the modification would still not produce the claimed invention. Instead, it would produce the same mixtures as before but with cryobarically killed *Listeria* instead of heat-killed *Listeria.*

Evans

Evans is also a secondary reference that was cited solely as teaching elements or limitations that are present in dependent claims 44-45 (namely that the dead *E. coli* was killed with a chemical such as alcohol). Specifically, the Examiner cites Evans for teaching that "dead *E. coli* containing therein any desired antigen are efficient vehicle [sic] in terms of delivering antigens to the gut immune system." According to the Examiner, Evans teaches that such *E. coli* can be killed by chemical treatment.

Applicant initially notes that the Examiner has given an inaccurate description of the teachings of Evans. Evans does not teach that "non-replicating dead *E. coli*" are efficient vaccine vehicles for "*any* desired antigen." This interpretation is far too broad. Instead, Evans teaches a highly specific vaccine against enterotoxigenic *E. coli* (ETEC) – e.g., see the title and

opening paragraph on page 117. The vaccine is prepared by treating an enterotoxigenic *E. coli* strain with colicin E2 which is a potent DNA endonuclease. Once treated with colicin E2, the *E. coli* cells lose all of their DNA (and thus the ability to replicate) but retain "a normal complement of antigens, including CFA/I and enterotoxin(s)." Accordingly, the "non-replicating dead *E. coli*" of Evans is not taught as a vehicle for generic antigens as the Examiner suggests but as a vehicle for specific CFA/I and enterotoxin(s) that are *endogenous* antigens of enterotoxigenic *E. coli*. As such, the Evans vaccine is a standard *attenuated* pathogenic bacterial vaccine that is designed to immunize recipients against the pathogenic bacterium *itself*.

In addition, instead of teaching the use of artificial chemicals to kill *E. coli* cells, Evans actually teaches *away* from this method. Indeed, as noted, Evans treated their *E. coli* cells with colicin E2 which is a potent DNA endonuclease. While colicin E2 could be characterized as a "chemical" it is not an artificial chemical in the same sense as claim 45 that covers iodine, bleach, ozone, and alcohol. Furthermore, once treated with colicin E2, the *E. coli* cells retain "a normal complement of antigens, including CFA/I and enterotoxin(s), *unaltered by chemical- or heat treatment*." Evans also note on page 118 that having "antigens *unaltered by artificial* treatment" is an "important [factor] determining successful gut immunization." Thus, again the Examiner's description of Evans is misleading.

Based on these narrow teachings it is unclear *how* a skilled person could actually combine the previously discussed teachings with those of Evans to produce the claimed invention. The Examiner suggests that the skilled person would "kill any *E. coli* expressing modified allergen as taught by the '799 patent, the ['978] publication and Yeung [...] by means of chemical treatment as taught by [...] Evans" (page 16 of final office action). This list of publications does not explain exactly how the teachings of each reference would be combined or modified. The only logical combinations of the teachings in these references that are apparent to Applicant are:

(a) treating the live *E. coli* cells of the '978 publication with colicin E2 as taught by Evans; or

(b) introducing the modified Ara h 2 of the '978 publication as a foreign antigen into the enterotoxigenic *E. coli* cells of Evans before these are killed with colicin E2.

As to combination (a), applicant fails to see *why* a skilled person would possibly have

been *motivated* to treat the live cells of the '978 publication with colicin E2. In the examples, the '978 publication explicitly teaches a method for preparing a "hypoallergenic" modified Ara h 2 *protein* vaccine. This modified Ara h 2 protein is made recombinantly in *E. coli* cells. Once the cells have been grown and the Ara h 2 protein expressed, the cells are lyzed and discarded by centrifugation. Why and when would a skilled person want to treat the cells with colicin E2 in this process? Treating the cells during fermentation would reduce the yield of Ara h 2. Treating the cells once fermentation is complete would be pointless since the next step involves lysing the cells. The Examiner may argue that a skilled person would want to use colicin E2 because Evans teaches that this produces a useful non-replicating bacterial vehicle. However, as noted above, this argument reads too much into the teachings of Evans. Evans teaches that the use of colicin E2 is useful in preparing a specific bacterial vaccine that includes endogenous antigens. Treatment with colicin E2 is crucial for their vaccine because it is a bacterial vaccine and the untreated bacterial cells are pathogenic. In contrast, the '978 publication describes a *protein* based vaccine. Based on the teachings of the '978 publication a skilled person would understand that the Ara h 2 protein portion is important while the bacterial portion is a mere production tool that can be discarded altogether. For all of these reasons, combination (a) cannot render the claims obvious.

As to combination (b), the motivation to combine the teachings is even less apparent. Certainly there would be no reason to replace the endogenous ETEC antigens with a modified peanut allergen such as Ara h 2. This would destroy the very purpose of the bacterial vaccine that is taught by Evans. In addition, there would be no apparent reason to add a modified peanut allergen such as Ara h 2 to the antigens already within the existing vaccine. Indeed, the whole purpose of Evans' vaccine is to build immunity against enterotoxigenic *E. coli*. Adding a modified peanut allergen would not improve the vaccine's ability to do this task. Accordingly there would be no motivation to make the proposed change. For all of these reasons, applicant also submits that combination (b) cannot render the claims obvious.

For all of these reasons, this rejection should also be removed.

Conclusion:

For the reasons presented above, it is respectfully submitted that the Examiner's

rejections have been overcome and thus that the amended claims are allowable. If the Examiner feels that a telephone interview would expedite the prosecution of this case towards allowance she is invited to contact the undersigned at 617-248-4793. In addition, please charge any fees that may be required, or credit any overpayment, to our Deposit Account No. 03-1721.

Respectfully Submitted,
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EXHIBIT A

2001 VERSION

Please refer to Pages 600-79 to 600-80

¶ 7.43 Objection to Claims, Allowable Subject Matter

Claim [1] objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

608.01(o) Basis for Claim Terminology in Description

The meaning of every term used in any of the claims should be apparent from the descriptive portion of the specification with clear disclosure as to its import; and in mechanical cases, it should be identified in the descriptive portion of the specification by reference to the drawing, designating the part or parts therein to which the term applies. A term used in the claims may be given a special meaning in the description. No term may be given a meaning repugnant to the usual meaning of the term.

Usually the terminology of the original claims follows the nomenclature of the specification, but sometimes in amending the claims or in adding new claims, new terms are introduced that do not appear in the specification. The use of a confusing variety of terms for the same thing should not be permitted.

New claims and amendments to the claims already in the application should be scrutinized not only for new matter but also for new terminology. While an applicant is not limited to the nomenclature used in the application as filed, he or she should make appropriate amendment of the specification whenever this nomenclature is departed from by amendment of the claims so as to have clear support or antecedent basis in the specification for the new terms appearing in the claims. This is necessary in order to insure certainty in construing the claims in the light of the specification, *Ex parte Kotler*, 1901 C.D. 62, 95 O.G. 2684 (Comm'r Pat. 1901). See 37 CFR 1.75, MPEP § 608.01(i) and § 1302.01.

The specification should be objected to if it does not provide proper antecedent basis for the claims by using form paragraph 7.44.

¶ 7.44 Claimed Subject Matter Not in Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: [1]

608.01(p) Completeness

Newly filed applications obviously failing to disclose an invention with the clarity required are discussed in MPEP § 702.01.

A disclosure in an application, to be complete, must contain such description and details as to enable any person skilled in the art or science to which the invention pertains to make and use the invention as of its filing date. *In re Glass*, 492 F.2d 1228, 181 USPQ 31 (CCPA 1974).

While the prior art setting may be mentioned in general terms, the essential novelty, the essence of the invention, must be described in such details, including proportions and techniques, where necessary, as to enable those persons skilled in the art to make and utilize the invention.

Specific operative embodiments or examples of the invention must be set forth. Examples and description should be of sufficient scope as to justify the scope of the claims. *Markush* claims must be provided with support in the disclosure for each member of the *Markush* group. Where the constitution and formula of a chemical compound is stated only as a probability or speculation, the disclosure is not sufficient to support claims identifying the compound by such composition or formula.

A complete disclosure should include a statement of utility. This usually presents no problem in mechanical cases. In chemical cases, varying degrees of specificity are required.

A disclosure involving a new chemical compound or composition must teach persons skilled in the art how to make the compound or composition. Incomplete teachings may not be completed by reference to subsequently filed applications.

For "Guidelines For Examination Of Applications For Compliance With The Utility Requirement of 35 U.S.C. 101," see MPEP § 2107.

For "General Principles Governing Utility Rejections," see MPEP § 2107.01.

For a discussion of the utility requirement under 35 U.S.C. 112, first paragraph, in drug cases, see MPEP § 2107.03 and § 2164.06(a).

For "Procedural Considerations Related to Rejections for Lack of Utility," see MPEP § 2107.02.

For "Special Considerations for Asserted Therapeutic or Pharmacological Utilities," see MPEP § 2107.03.

I. INCORPORATION BY REFERENCE

The Commissioner has considerable discretion in determining what may or may not be incorporated by reference in a patent application. *General Electric Co. v. Brenner*, 407 F.2d 1258, 159 USPQ 335 (D.C. Cir. 1968). The incorporation by reference practice with respect to applications which issue as U.S. patents provides the public with a patent disclosure which minimizes the public's burden to search for and obtain copies of documents incorporated by reference which may not be readily available. Through the Office's incorporation by reference policy, the Office ensures that reasonably complete disclosures are published as U.S. patents. The following is the manner in which the Commissioner has elected to exercise that discretion. Section A provides the guidance for incorporation by reference in applications which are to issue as U.S. patents. Section B provides guidance for incorporation by reference in benefit applications; i.e., those domestic (35 U.S.C. 120) or foreign (35 U.S.C. 119(a)) applications relied on to establish an earlier effective filing date.

A. *Review of Applications Which Are To Issue as Patents.*

An application as filed must be complete in itself in order to comply with 35 U.S.C. 112. Material nevertheless may be incorporated by reference, *Ex parte Schwarze*, 151 USPQ 426 (Bd. App. 1966). An application for a patent when filed may incorporate "essential material" by reference to (1) a U.S. patent, (2) a U.S. patent application publication, or (3) a pending U.S. application, subject to the conditions set forth below.

"Essential material" is defined as that which is necessary to (1) describe the claimed invention, (2) provide an enabling disclosure of the claimed invention, or (3) describe the best mode (35 U.S.C. 112). In any application which is to issue as a U.S. patent, essential material may not be incorporated by reference to (1) patents or applications published by foreign countries or a regional patent office, (2) non-patent publications, (3) a U.S. patent or application which itself incorporates "essential material" by reference, or (4) a foreign application.

Nonessential subject matter may be incorporated by reference to (1) patents or applications published by the United States or foreign countries or regional patent offices, (2) prior filed, commonly owned U.S. applications, or (3) non-patent publications however, hyperlinks and/or other forms of browser executable code cannot be incorporated by reference. See MPEP § 608.01. Nonessential subject matter is subject matter referred to for purposes of indicating the background of the invention or illustrating the state of the art.

Mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph. *In re de Seversky*, 474 F.2d 671, 177 USPQ 144 (CCPA 1973). In addition to other requirements for an application, the referencing application should include an identification of the referenced patent, application, or publication. Particular attention should be directed to specific portions of the referenced document where the subject matter being incorporated may be found. Guidelines for situations where applicant is permitted to fill in a number for Application No. _____ left blank in the application as filed can be found in *In re Fouche*, 439 F.2d 1237, 169 USPQ 429 (CCPA 1971) (Abandoned applications less than 20 years old can be incorporated by reference to the same extent as copending applications; both types are open to the public upon the referencing application issuing as a patent. See MPEP § 103).

1. Complete Disclosure Filed

If an application is filed with a complete disclosure, essential material may be canceled by amendment and may be substituted by reference to a U.S. patent or an earlier filed pending U.S. application. The amendment must be accompanied by an affidavit or declaration signed by the applicant, or a practitioner representing the applicant, stating that the material canceled from the application is the same material that has been incorporated by reference.

If an application as filed incorporates essential material by reference to a U.S. patent or a pending and commonly owned U.S. application, applicant may be required prior to examination to furnish the Office with a copy of the referenced material together with an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the copy consists of the same material incorporated by reference in the referencing application.

However, if a copy of a printed U.S. patent is furnished, no affidavit or declaration is required.

Prior to allowance of an application that incorporates essential material by reference to a pending U.S. application, the examiner shall determine if the referenced application has been published or issued as a patent. If the referenced application has been published or issued as a patent, the examiner shall enter the U.S. Patent Application Publication No. or the U.S. Patent No. of the referenced application in the specification of the referencing application (see MPEP § 1302.04). If the referenced application has not been published or issued as a patent, applicant will be required to amend the disclosure of the referencing application to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating the amendatory material consists of the same material incorporated by reference in the referencing application.

2. Improper Incorporation

The filing date of any application wherein essential material is improperly incorporated by reference to a foreign application or patent or to a publication will not be affected because of the reference. In such a case, the applicant will be required to amend the specification to include the material incorporated by reference. The following form paragraphs may be used.

¶ 6.19 Incorporation by Reference, Foreign Patent or Application

The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

¶ 6.19.01 Improper Incorporation by Reference, General

The attempt to incorporate subject matter into this application by reference to [1] is improper because [2].

Examiner Note:

1. In bracket 1, identify the document such as an application or patent number or other identification.

2. In bracket 2, give reason why it is improper.

The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. In re Hawkins, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); In re Hawkins, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); In re Hawkins, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

Reliance on a commonly assigned copending application by a different inventor may ordinarily be made for the purpose of completing the disclosure. See *In re Fried*, 329 F.2d 323, 141 USPQ 27 (CCPA 1964), and *General Electric Co. v. Brenner*, 407 F.2d 1258, 159 USPQ 335 (D.C. Cir. 1968).

Since a disclosure must be complete as of the filing date, subsequent publications or subsequently filed applications cannot be relied on to establish a constructive reduction to practice or an enabling disclosure as of the filing date. *White Consol. Indus., Inc. v. Vega Servo-Control, Inc.*, 713 F.2d 788, 218 USPQ 961 (Fed. Cir. 1983); *In re Scarbrough*, 500 F.2d 560, 182 USPQ 298 (CCPA 1974); *In re Glass*, 492 F.2d 1228, 181 USPQ 31 (CCPA 1974).

B. Review of Applications Which Are Relied on To Establish an Earlier Effective Filing Date.

The limitations on the material which may be incorporated by reference in U.S. patent applications which are to issue as U.S. patents do not apply to applications relied on only to establish an earlier effective filing date under 35 U.S.C. 119 or 35 U.S.C. 120. Neither 35 U.S.C. 119(a) nor 35 U.S.C. 120 places any restrictions or limitations as to how the claimed invention must be disclosed in the earlier application to comply with 35 U.S.C. 112, first paragraph. Accordingly, an application is entitled to rely upon the filing date of an earlier application, even if the earlier application itself incorporates essential material by reference to another document. See *Ex parte Maziere*, 27 USPQ2d 1705, 1706-07 (Bd. Pat. App. & Inter. 1993).

The reason for incorporation by reference practice with respect to applications which are to issue as U.S. patents is to provide the public with a patent disclosure which minimizes the public's burden to search for and obtain copies of documents incorporated by

reference which may not be readily available. Through the Office's incorporation by reference policy, the Office ensures that reasonably complete disclosures are published as U.S. patents. The same policy concern does not apply where the sole purpose for which an applicant relies on an earlier U.S. or foreign application is to establish an earlier filing date. Incorporation by reference in the earlier application of (1) patents or applications published by foreign countries or regional patent offices, (2) nonpatent publications, (3) a U.S. patent or application which itself incorporates "essential material" by reference, or (4) a foreign application, is not critical in the case of a "benefit" application.

When an applicant, or a patent owner in a reexamination or interference, claims the benefit of the filing date of an earlier application which incorporates material by reference, the applicant or patent owner may be required to supply copies of the material incorporated by reference. For example, an applicant may claim the benefit of the filing date of a foreign application which itself incorporates by reference another earlier filed foreign application. If necessary, due to an intervening reference, applicant should be required to supply a copy of the earlier filed foreign application, along with an English language translation. A review can then be made of the foreign application and all material incorporated by reference to determine whether the foreign application discloses the invention sought to be patented in the manner required by the first paragraph of 35 U.S.C. 112 so that benefit may be accorded. *In re Gosteli*, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989).

II. SIMULATED OR PREDICTED TEST RESULTS OR PROPHETIC EXAMPLES

Simulated or predicted test results and prophetical examples (paper examples) are permitted in patent applications. Working examples correspond to work actually performed and may describe tests which have actually been conducted and results that were achieved. Paper examples describe the manner and process of making an embodiment of the invention which has not actually been conducted. Paper examples should not be represented as work actually done. No results should be represented as actual results unless they have actually been achieved. Paper examples should not be described using the past tense.

For problems arising from the designation of materials by trademarks and trade names, see MPEP § 608.01(v).

608.01(q) Substitute or Rewritten Specification

37 CFR 1.125. Substitute specification.

(a) If the number or nature of the amendments or the legibility of the application papers renders it difficult to consider the application, or to arrange the papers for printing or copying, the Office may require the entire specification, including the claims, or any part thereof, be rewritten.

(b) A substitute specification, excluding the claims, may be filed at any point up to payment of the issue fee if it is accompanied by:

(1) A statement that the substitute specification includes no new matter; and

(2) A marked up version of the substitute specification showing all the changes (including the matter being added to and the matter being deleted from) to the specification of record. Numbering the paragraphs of the specification of record is not considered a change that must be shown pursuant to this paragraph.

(c) A substitute specification submitted under this section must be submitted in clean form without markings as to amended material. The paragraphs of any substitute specification, other than the claims, should be individually numbered in Arabic numerals so that any amendment to the specification may be made by replacement paragraph in accordance with § 1.121(b)(1).

(d) A substitute specification under this section is not permitted in a reissue application or in a reexamination proceeding.

The specification is sometimes in such faulty English that a new specification is necessary; in such instances, a new specification should be required.

Form paragraph 6.28 may be used where the specification is in faulty English.

¶ 6.28 Idiomatic English

A substitute specification in proper idiomatic English and in compliance with 37 CFR 1.52(a) and (b) is required. The substitute specification filed must be accompanied by a statement that it contains no new matter.

37 CFR 1.125(a) applies to a substitute specification required by the Office. If the number or nature of the amendments or the legibility of the application papers renders it difficult to consider the application, or to arrange the papers for printing or copying, the Office may require the entire specification, including the claims, or any part thereof be rewritten.

EXHIBIT B

CURRENT VERSION

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608.01(p) Completeness [R-3] - 600 Parts, Form, and Content of Application

608.01(p) Completeness [R-3]

Newly filed applications obviously failing to disclose an invention with the clarity required are discussed in **MPEP § 702.01**.

A disclosure in an application, to be complete, must contain such description and details as to enable any person skilled in the art or science to which the invention pertains to make and use the invention as of its filing date. *In re Glass,* 492 F.2d 1228, 181 USPQ 31 (CCPA 1974).

While the prior art setting may be mentioned in general terms, the essential novelty, the essence of the invention, must be described in such details, including proportions and techniques, where necessary, as to enable those persons skilled in the art to make and utilize the invention.

Specific operative embodiments or examples of the invention must be set forth. Examples and description should be of sufficient scope as to justify the scope of the claims. *Markush* claims must be provided with support in the disclosure for each member of the *Markush* group. Where the constitution and formula of a chemical compound is stated only as a probability or speculation, the disclosure is not sufficient to support claims identifying the compound by such composition or formula.

A complete disclosure should include a statement of utility. This usually presents no problem in mechanical cases. In chemical cases, varying degrees of specificity are required.

A disclosure involving a new chemical compound or composition must teach persons skilled in the art how to make the compound or composition. Incomplete teachings may not be completed by reference to subsequently filed applications.

For "Guidelines For Examination Of Applications For Compliance With The Utility Requirement of **35 U.S.C. 101**," see **MPEP § 2107**.

For "General Principles Governing Utility Rejections," see **MPEP § 2107.01**.

For a discussion of the utility requirement under **35 U.S.C. 112**, first paragraph, in drug cases, see **MPEP § 2107.03** and **§ 2164.06(a)**.

For "Procedural Considerations Related to Rejections for Lack of Utility," see **MPEP § 2107.02**.

For "Special Considerations for Asserted Therapeutic or Pharmacological Utilities," see **MPEP § 2107.03**.

I. INCORPORATION BY REFERENCE

>

37 CFR 1.57 Incorporation by reference.

(a) Subject to the conditions and requirements of this paragraph, if all or a portion of the specification or drawing(s) is inadvertently omitted from an application, but the application contains a claim under § 1.55 for priority of a prior-filed foreign application, or a claim under § **1.78** for the benefit of a prior-filed provisional, nonprovisional, or international application, that was present on the filing date of the application, and the inadvertently omitted portion of the specification or drawing(s) is completely contained in the prior-filed application, the claim under § **1.55** or § 1.78 shall also be considered an incorporation by reference of the prior-filed application as to the inadvertently omitted portion of the specification or drawing(s).

(1) The application must be amended to include the inadvertently omitted portion of the specification or drawing(s) within any time period set by the Office, but in no case later than the close of prosecution as defined by § **1.114** (b), or abandonment of the application, whichever occurs earlier. The applicant is also required to:

(i) Supply a copy of the prior-filed application, except where the prior-filed application is an application filed under **35 U.S.C. 111**;

(ii) Supply an English language translation of any prior-filed application that is in a language other than English; and

(iii) Identify where the inadvertently omitted portion of the specification or drawings can be found in the prior-filed application.

(2) Any amendment to an international application pursuant to this paragraph shall be effective only as to the United States, and shall have no effect on the international filing date of the application. In addition, no request to add the inadvertently omitted portion of the specification or drawings in an international application designating the United States will be acted upon by the Office prior to the entry and commencement of the national stage (§ 1.491) or the filing of an application under **35 U.S.C. 111** (a) which claims benefit of the international application.

(3) If an application is not otherwise entitled to a filing date under § **1.53**(b), the amendment must be by way of a petition pursuant to this paragraph accompanied

by the fee set forth in § **1.17**(f).

(b) Except as provided in paragraph (a) of this section, an incorporation by reference must be set forth in the specification and must:

(1) Express a clear intent to incorporate by reference by using the root words "incorporat(e)" and "reference" (*e.g.*, "incorporate by reference"); and

(2) Clearly identify the referenced patent, application, or publication.

(c) "Essential material" may be incorporated by reference, but only by way of an incorporation by reference to a U.S. patent or U.S. patent application publication, which patent or patent application publication does not itself incorporate such essential material by reference. "Essential material" is material that is necessary to:

(1) Provide a written description of the claimed invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and set forth the best mode contemplated by the inventor of carrying out the invention as required by the first paragraph of **35 U.S.C. 112**;

(2) Describe the claimed invention in terms that particularly point out and distinctly claim the invention as required by the second paragraph of **35 U.S.C. 112**; or

(3) Describe the structure, material, or acts that correspond to a claimed means or step for performing a specified function as required by the sixth paragraph of **35 U.S.C. 112**.

(d) Other material ("Nonessential material") may be incorporated by reference to U.S. patents, U.S. patent application publications, foreign patents, foreign published applications, prior and concurrently filed commonly owned U.S. applications, or non-patent publications. An incorporation by reference by hyperlink or other form of browser executable code is not permitted.

(e) The examiner may require the applicant to supply a copy of the material incorporated by reference. If the Office requires the applicant to supply a copy of material incorporated by reference, the material must be accompanied by a statement that the copy supplied consists of the same material incorporated by reference in the referencing application.

(f) Any insertion of material incorporated by reference into the specification or drawings of an application must be by way of an amendment to the specification or drawings. Such an amendment must be accompanied by a statement that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter.

(g) An incorporation of material by reference that does not comply with paragraphs (b), (c), or (d) of this section is not effective to incorporate such material unless corrected within any time period set by the Office, but in no case later than the

close of prosecution as defined by § **1.114**(b), or abandonment of the application, whichever occurs earlier. In addition:

(1) A correction to comply with paragraph (b)(1) of this section is permitted only if the application as file d clearly conveys an intent to incorporate the material by reference. A mere reference to material does not convey an intent to incorporate the material by reference.

(2) A correction to comply with paragraph (b)(2) of this section is only permitted for material that was sufficiently described to uniquely identify the document.<

The Director has considerable discretion in determining what may or may not be incorporated by reference in a patent application. *General Electric Co. v. Brenner*, 407 F.2d 1258, 159 USPQ 335 (D.C. Cir. 1968). >Effective October 21, 2004, the Office codified in 37 CFR **1.57**(b) - (g) existing practice with respect to explicit incorporations by reference with a few changes to reflect the eighteen-month publication of applications. In addition, 37 CFR **1.57**(a) was added to provide a safeguard for applicants when a page(s) of the specification, or a portion thereof, or a sheet(s) of the drawing(s), or a portion thereof, is inadvertently omitted from an application, such as through a clerical error. 37 CFR **1.57**(a) applies to applications filed on or after September 21, 2004. 37 CFR **1.57**(a) permits inadvertently omitted material to be added to the application by way of a later filed amendment if the inadvertently omitted portion of the specification or drawing(s) is completely contained in a prior-filed application (for which priority/benefit is claimed) even though there is no explicit incorporation by reference of the prior-filed application. See MPEP § **201.17** for discussion regarding 37 CFR **1.57**(a).<

The incorporation by reference practice with respect to applications which issue as U.S. patents provides the public with a patent disclosure which minimizes the public's burden to search for and obtain copies of documents incorporated by reference which may not be readily available. Through the Office's incorporation by reference policy, the Office ensures that reasonably complete disclosures are published as U.S. patents. The following is the manner in which the Director has elected to exercise that discretion. Section A provides the guidance for incorporation by reference in applications which are to issue as U.S. patents. Section B provides guidance for incorporation by reference in benefit applications; i.e., those domestic (**35 U.S.C. 120**) or foreign (**35 U.S.C. 119(a)**) applications relied on to establish an earlier effective filing date. See MPEP § **2181** for the impact of incorporation by reference on the determination of whether applicant has complied with the requirements of 35 U.S.C. **112**, second paragraph when 35 U.S.C. **112**, sixth paragraph is invoked.

A. Review of Applications Which Are To Issue as Patents.

An application as filed must be complete in itself in order to comply with **35 U.S.C. 112**. Material nevertheless may be incorporated by reference, *Ex parte Schwarze*, 151 USPQ 426 (Bd. App. 1966). An application for a patent when filed may incorporate "essential material" by reference to (1) a U.S. patent, >or< (2) a U.S.

patent application publication, **>which patent or patent application publication does not itself incorporate such essential material by reference. See 37 CFR **1.57** (c). Prior to October 21, 2004, Office policy also permitted incorporation by reference to< a pending U.S. application**.

"Essential material" is defined >in 37 CFR **1.57**(c)< as that which is necessary to (1) **>provide a written description of the claimed invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and set forth the best mode contemplated by the inventor of carrying out the invention as required by the first paragraph of 35 U.S.C. **112**, (2) describe the claimed invention in terms that particularly point out and distinctly claim the invention as required by the second paragraph of 35 U.S.C. **112**, or (3) describe the structure, material, or acts that correspond to a claimed means or step for performing a specified function as required by the sixth paragraph of 35 U.S.C. **112**. In any application that is to issue as a U.S. patent, essential material may only be incorporated by reference to a U.S. patent or patent application publication. The practice of permitting incorporation by reference of material from unpublished applications in which the issue fee was paid was discontinued by rule on October 21, 2004.

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Other material ("nonessential subject matter")< may be incorporated by reference to (1) patents or applications published by the United States or foreign countries or regional patent offices, (2) prior >and concurrently< filed, commonly owned U.S. applications, or (3) non-patent publications **. Nonessential subject matter is subject matter referred to for purposes of indicating the background of the invention or illustrating the state of the art.

>

An incorporation by reference by hyperlink or other form of browser executable code is not permitted. See 37 CFR **1.57**(d) and MPEP § **608.01**.

<

Mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by **35 U.S.C. 112**, first paragraph. *In re de Seversky*, 474 F.2d 671, 177 USPQ 144 (CCPA 1973). >37 CFR **1.57**(b)(1) limits a proper incorporation by reference (except as provided in 37 CFR **1.57**(a)) to instances only where the perfecting words "incorporated by reference" or the root of the words "incorporate" (e.g., incorporating, incorporated) and "reference" (e.g., referencing) appear. The requirement for specific root words will bring greater clarity to the record and provide a bright line test as to where something is being referred to is an incorporation by reference. The Office intends to treat references to documents that do not meet this "bright line" test as noncompliant incorporations by reference and may require correction pursuant to 37 CFR **1.57**(g). If a reference to a document does not clearly indicate an intended incorporation by reference, examination will proceed as if no incorporation by reference statement has been made and the Office will not expend resources trying to determine if an

incorporation by reference was intended.< In addition to other requirements for an application, the referencing application *>must< include an identification of the referenced patent, application, or publication. >See 37 CFR **1.57**(b)(2)< Particular attention should be directed to specific portions of the referenced document where the subject matter being incorporated may be found. Guidelines for situations where applicant is permitted to fill in a number for Application No. _____ left blank in the application as filed can be found in *In re Fouche,* 439 F.2d 1237, 169 USPQ 429 (CCPA 1971) (Abandoned applications less than 20 years old can be incorporated by reference to the same extent as copending applications; both types are open to the public upon the referencing application issuing as a patent. See >37 CFR **1.14**(a)(i)(iv) and (vi) and< **MPEP § 103**).

1. Complete Disclosure Filed

If an application is filed with a complete disclosure, essential material may be canceled by amendment and may be substituted by reference to a U.S. patent or **>a U.S. patent application publication.< The amendment must be accompanied by **>a statement< signed by the applicant, or a practitioner representing the applicant, stating that the material canceled from the application is the same material that has been incorporated by reference>and no new matter has been included (see 37 CFR **1.57**(f). The same procedure is available for nonessential material.<

If an application as filed incorporates * material by reference **>, a copy of the incorporated by reference material may be required to be submitted to the Office even if the material is properly incorporated by reference. The examiner may require a copy of the incorporated material to review and to understand what is being incorporated or to put the description of the material in its proper context. Another instance where a copy of the incorporated material may be required is where the material is being inserted by amendment into the body of the application to replace an improper incorporation by reference statement so that the Office can determine that the material being added by amendment in lieu of the incorporation is the same material as was attempted to be incorporated. If the Office requires the applicant to supply a copy of the material incorporated by reference, the material must be accompanied by a statement that the copy supplied consists of the same material incorporated by reference in the referencing application. See 37 CFR **1.57** (e).<

2. Improper Incorporation

**

>37 CFR **1.57**(f) addresses corrections of incorporation by reference by inserting the material previously incorporated by reference. A noncompliant incorporation by reference statement may be corrected by an amendment. 37 CFR **1.57**(f). However, the amendment must not include new matter. Incorporating by reference material that was not incorporated by reference on filing of an application may introduce new matter. An incorporation by reference of essential material to an unpublished U.S. patent application, a foreign application or patent, or to a publication is improper under 37 CFR **1.57**(c). The improper incorporation by

reference is not effective to incorporate the material unless corrected by the applicant (37 CFR **1.57**(g)). Any underlying objection or rejection (e.g., under 35 U.S.C. **112**) should be made by the examiner until applicant corrects the improper incorporation by reference by submitting an amendment to amend the specification or drawings to include the material incorporated by reference. A statement that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter is also required. 37 CFR **1.57**(f). See also *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973). Improper incorporation by reference statements and late corrections thereof require expenditure of unnecessary examination resources and slow the prosecution process. Applicants know (or should know) whether they want material incorporated by reference, and must timely correct any incorporation by reference errors. Correction must be done within the time period set forth in 37 CFR **1.57**(g).

An incorporation by reference that does not comply with 37 CFR **1.57**(b), (c), or (d) is not effective to incorporate such material unless corrected within any time period set by the Office (should the noncompliant incorporation by reference be first noticed by the Office and applicant informed thereof), but in no case later than the close of prosecution as defined by 37 CFR **1.114**(b) (should applicant be the first to notice the noncompliant incorporation by reference and the Office informed thereof), or abandonment of the application, whichever occurs earlier. The phrase "or abandonment of the application" is included in 37 CFR **1.57**(g) to address the situations where an application is abandoned prior to the close of prosecution, e.g., the situation where an application is abandoned after a non-final Office action.

37 CFR **1.57**(g)(1) authorizes the correction of noncompliant incorporation by reference statements that do not use the root of the words "incorporate" and "reference" in the incorporation by reference statement. This correction cannot be made when the material was merely referred to and there was no clear specific intent to incorporate it by reference.

37 CFR **1.57**(g)(2) states that a citation of a document can be corrected where the document is sufficiently described to uniquely identify the document. Correction of a citation for a document that cannot be identified as the incorporated document may be new matter and is not authorized by 37 CFR **1.57**(g)(2). An example would be where applicant intended to incorporate a particular journal article but supplied the citation information for a completely unrelated book by a different author, and there is no other information to identify the correct journal article. Since it cannot be determined from the citation originally supplied what article was intended to be incorporated, it would be improper (e.g., new matter) to replace the original incorporation by reference with the intended incorporation by reference. A citation of a patent application by attorney docket number, inventor name, filing date and title of invention may sufficiently describe the document, but even then correction should be made to specify the application number.

A petition under 37 CFR **1.183** to suspend the time period requirement set forth in 37 CFR **1.57**(g) will not be appropriate. After the application has been abandoned, applicant must file a petition to revive under 37 CFR **1.137** for the purpose of

correcting the incorporation by reference. After the application has issued as a patent, applicant may correct the patent by filing a reissue application. Correcting an improper incorporation by reference with a certificate of correction is not an appropriate means of correction because it may alter the scope of the claims. The scope of the claims may be altered because 37 CFR **1.57**(g) provides that an incorporation by reference that does not comply with paragraph (b), (c), or (d) is not an effective incorporation. For example, an equivalent means omitted from a patent disclosure by an ineffective incorporation by reference would be outside the scope of the patented claims. Hence, a correction of an incorporation by reference pursuant to 37 CFR **1.57** may alter the scope of the claims by adding the omitted equivalent means. Changes involving the scope of the claims should be done via the reissue process. Additionally, the availability of the reissue process for corrections would make a successful showing required under 37 CFR **1.183** unlikely. The following examples show when an improper incorporation by reference is required to be corrected:

Example 1:

Upon review of the specification, the examiner noticed that the specification included an incorporation by reference statement incorporating essential material disclosed in a foreign patent. In a non-final Office action, the examiner required the applicant to amend the specification to include the essential material.

In reply to the non-final Office action, applicant must correct the improper incorporation by reference by filing an amendment to add the essential material disclosed in the foreign patent and a statement in compliance with 37 CFR **1.57**(f) within the time period for reply set forth in the non-final Office action.

Example 2:

Upon review of the specification, the examiner determined that the subject matter incorporated by reference from a foreign patent was "nonessential material" and therefore, did not object to the incorporation by reference. In reply to a non-final Office action, applicant filed an amendment to the claims to add a new limitation that was supported only by the foreign patent. The amendment filed by the applicant caused the examiner to re-determine that the incorporated subject matter was "essential material" under 37 CFR **1.57**(c). The examiner rejected the claims that include the new limitation under 35 U.S.C. **112**, first paragraph, in a final Office action.

Since the rejection under 35 U.S.C. **112**, first paragraph was necessitated by the applicant's amendment, the finality of the Office action is proper. If the applicant wishes to overcome the rejection under 35 U.S.C. **112**, first paragraph by filing an amendment under 37 CFR **1.57**(f) to add the subject material disclosed in the foreign patent into the specification, applicant may file the amendment as an after final amendment in compliance with 37 CFR **1.116**. Alternatively, applicant may file an RCE under 37 CFR **1.114** accompanied by the appropriate fee, and an amendment per 37 CFR **1.57**(f) within the time period for reply set forth in the final Office action.

The following form paragraphs may be used:

¶ 6.19 Incorporation by Reference, Unpublished U.S. Application, Foreign Patent or Application, Publication

The incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 CFR **1.57**(f).

Examiner Note

Since the material that applicant is attempting to incorporate in the specification is considered to be essential material, an appropriate objection to the specification and/or rejection of the claim(s) under 35 U.S.C. **112**, should be made. One or more of form paragraphs **7.31.01** to **7.31.04,** as for example, should be used following this form paragraph.

¶ 6.19.01 Ineffective Incorporation by Reference, General

The attempt to incorporate subject matter into this application by reference to **[1]** is ineffective because **[2]**.

Examiner Note

1. In bracket 1, identify the document such as an application or patent number or other identification.

2. In bracket 2, give reason(s) why it is ineffective (e.g., the root words "incorporate" and/or "reference" have been omitted, see 37 CFR 1.57(b)(1); the reference document is not clearly identified as required by 37 CFR 1.57(b)(2)).

3. This form paragraph should be followed by form paragraph **6.19.03**.

¶ 6.19.03 Correction of Ineffective Incorporation by Reference

The incorporation by reference will not be effective until correction is made to comply with **37 CFR 1.57**(b), (c), or (d). If the incorporated material is relied upon to meet any outstanding objection, rejection, or other requirement imposed by the Office, the correction must be made within any time period set by the Office for responding to the objection, rejection, or other requirement for the incorporation to be effective. Compliance will not be held in abeyance with respect to responding to the objection, rejection, or other requirement for the incorporation to be effective. In no case may the correction be made later than the close of prosecution as defined in **37 CFR 1.114**(b), or abandonment of the application, whichever occurs earlier.

Any correction inserting material by amendment that was previously incorporated by reference must be accompanied by a statement that the material being inserted is the material incorporated by reference and the amendment contains no new matter. **37 CFR 1.57**(f).

The filing date of any application wherein essential material is improperly incorporated by reference will not be affected by applicant's correction where (A) there is a clear intent to incorporate by reference the intended material and the correction is to add the root words of "incorporate" and "reference," (B) the incorporated document can be uniquely identified and the correction is to clarify the document's identification, and (C) where the correction is to insert the material from the reference where incorporation is to an unpublished U.S. patent application, foreign application or patent, or to a publication.<

Reliance on a commonly assigned >, prior filed or concurrently filed< copending application by a different inventor may ordinarily be made for the purpose of completing the disclosure>provided the incorporated material is directed to nonessential material. See 37 CFR **1.57**(d)<. See *In re Fried*, 329 F.2d 323, 141 USPQ 27 (CCPA 1964), and *General Electric Co. v. Brenner*, 407 F.2d 1258, 159 USPQ 335 (D.C. Cir. 1968).

Since a disclosure must be complete as of the filing date, subsequent publications or subsequently filed applications cannot be relied on to establish a constructive reduction to practice or an enabling disclosure as of the filing date. *White Consol. Indus., Inc. v. Vega Servo-Control, Inc.*, 713 F.2d 788, 218 USPQ 961 (Fed. Cir. 1983); *In re Scarbrough*, 500 F.2d 560, 182 USPQ 298 (CCPA 1974); *In re Glass,* 492 F.2d 1228, 181 USPQ 31 (CCPA 1974).

B. Review of Applications Which Are Relied on To Establish an Earlier Effective Filing Date.

The limitations on the material which may be incorporated by reference in U.S. patent applications which are to issue as U.S. patents do not apply to applications relied on only to establish an earlier effective filing date under **35 U.S.C. 119** or **35 U.S.C. 120**. Neither **35 U.S.C. 119(a)** nor **35 U.S.C. 120** places any restrictions or limitations as to how the claimed invention must be disclosed in the earlier application to comply with **35 U.S.C. 112**, first paragraph. Accordingly, an application is entitled to rely upon the filing date of an earlier application, even if the earlier application itself incorporates essential material by reference to another document. See *Ex parte Maziere*, 27 USPQ2d 1705, 1706-07 (Bd. Pat. App. & Inter. 1993).

The reason for incorporation by reference practice with respect to applications which are to issue as U.S. patents is to provide the public with a patent disclosure which minimizes the public's burden to search for and obtain copies of documents incorporated by reference which may not be readily available. Through the Office's incorporation by reference policy, the Office ensures that reasonably complete disclosures are published as U.S. patents. The same policy concern does not apply where the sole purpose for which an applicant relies on an earlier U.S. or foreign application is to establish an earlier filing date. Incorporation by reference in the

earlier application of (1) patents or applications published by foreign countries or regional patent offices, (2) nonpatent publications, (3) a U.S. patent or application which itself incorporates "essential material" by reference, or (4) a foreign application, is not critical in the case of a "benefit" application.

When an applicant, or a patent owner in a reexamination or interference, claims the benefit of the filing date of an earlier application which incorporates material by reference, the applicant or patent owner may be required to supply copies of the material incorporated by reference. For example, an applicant may claim the benefit of the filing date of a foreign application which itself incorporates by reference another earlier filed foreign application. If necessary, due to an intervening reference, applicant should be required to supply a copy of the earlier filed foreign application, along with an English language translation. A review can then be made of the foreign application and all material incorporated by reference to determine whether the foreign application discloses the invention sought to be patented in the manner required by the first paragraph of **35 U.S.C. 112** so that benefit may be accorded. *In re Gosteli*, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989).

As a safeguard against the omission of a portion of a prior application for which priority is claimed under 35 U.S.C. **119**(a)-(d) or (f), or for which benefit is claimed under 35 U.S.C. **119**(e) or **120**, applicant may include a statement at the time of filing of the later application incorporating by reference the prior application. See MPEP § **201.06(c)** >and § **201.11**< where domestic benefit is claimed. See MPEP § **201.13** where foreign priority is claimed. >See MPEP § **201.17** regarding 37 CFR **1.57**(a) for applications filed on or after September 21, 2004.< The inclusion of such an incorporation by reference statement in the later-filed application will permit applicant to include subject matter from the prior application into the later-filed application without the subject matter being considered as new matter. For the incorporation by reference to be effective as a proper safeguard, the incorporation by reference statement must be filed at the time of filing of the later-filed application. An incorporation by reference statement added after an application's filing date is not effective because no new matter can be added to an application after its filing date (see 35 U.S.C. **132**(a).

II. SIMULATED OR PREDICTED TEST RESULTS OR PROPHETIC EXAMPLES

Simulated or predicted test results and prophetical examples (paper examples) are permitted in patent applications. Working examples correspond to work actually performed and may describe tests which have actually been conducted and results that were achieved. Paper examples describe the manner and process of making an embodiment of the invention which has not actually been conducted. Paper examples should not be represented as work actually done. No results should be represented as actual results unless they have actually been achieved. Paper examples should not be described using the past tense. *Hoffman-La Roche, Inc. v. Promega Corp.*, 323 F.3d 1354, 1367, 66 USPQ2d 1385, 1394 (Fed. Cir. 2003).

For problems arising from the designation of materials by trademarks and trade names, see **MPEP § 608.01(v)**.

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